codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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CX 5/20

**CL 2005/56-NFSDU**
**December 2005**

**TO:** Codex Contact Points
Interested International Organizations

**FROM:** Secretary, Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme
FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy

**SUBJECT:** **PROPOSED DRAFT RECOMMENDATIONS ON THE SCIENTIFIC BASIS OF HEALTH CLAIMS AT STEP 2/3**

**DEADLINE:** **31 March 2006**

**COMMENTS:**

**To:**
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## BACKGROUND

1. The 27th session of Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) held in Bonn, Germany, 21 - 25 November 2005, could not discuss the document CX/NFSDU 05/27/9 in detail due to time constraints. The Committee agreed to return the Proposed Draft Recommendations to Step 2/3 for redrafting by the Delegation of France in the light of the comments received, for further consideration at the next session.[1]

2. In its capacity as the chair of the Electronic Drafting Group, the Delegation of France provided a summary of the main issues raised in the written comments submitted, before the 27th session, on the document CX/NFSDU 05/27/9 (July 2005). This summary has been circulated during this session in Conference Room Document (CRD 10). It was agreed that a Circular Letter listing the questions to be

[1] ALINORM 06/29/26 – para. 146 & 147.

addressed would be issued on the basis of this summary, for comments with a deadline of 31 March 2006, to be sent to the Delegation of France.

3. All the written comments, available at the 27th session of the Committee, are found in the working document CX/NFSDU 05/27/9-Add.1 (comments of Argentina, Australia, Bolivia, Brazil, Mexico, New Zealand, Republic of Korea, United States, CIAA, IADSA, IFCGA, ILSI, ISDI) and in Conference Room Documents: CRD 10 (comments of Canada, Denmark, Germany, Indonesia, Kenya, South Africa, United States, EFLA) and CRD 19 (comments of ICGMA).

4. As regards the Scope of the document, the Committee noted that some written comments proposed to expand the Scope to cover authorization procedures, but agreed that such procedures were the responsibility of national authorities. The Committee **confirmed** that the Proposed Draft Recommendations were intended to address the nature of the scientific evidence required to substantiate claims, in accordance with the mandate given by the Commission when new work had been approved.

5. The Committee noted a proposal to make the safety requirements mandatory, however several delegations and observers pointed out that all foods placed on the market should be safe and that food safety as such should not be addressed in the document. The Committee recalled that food safety was addressed in other Codex texts and **confirmed** that the purpose of the document was to address the issues related to the scientific substantiation of health claims, and only the safety issues directly related to the claims required specific consideration.

6. The Delegation of France recalled that three types of health claims were allowed and highlighted the issues relating to the type of scientific evidence required, which might differ according to the claim concerned. The Committee **noted that the need for human studies and the use of biomarkers would need further consideration** but could not discuss these issues in detail at this stage. The Delegation of the US indicated that risk assessments relating to health claims might be more appropriate than safety issues.

7. The Delegation of the United States drew the attention of the Committee to its written comments based on its experience at the national level with the regulation of health claims. The Delegation of the UK (speaking on behalf of EC Member Countries) informed the Committee that a draft regulation was under development and that it included disease reduction claims. The Observer from IADSA noted the relevance of the publication on the PASSCLAIM (Process for the Assessment of the Assessment of Scientific Support for Claims on Foods) project that was made available to delegates at the session. It was suggested that sufficient time be allowed for discussion of this agenda item at the next session.

8. The Committee **agreed** that further progress on this issue at its next session required careful consideration of several key issues, listed hereunder, based on the comments received from Members and Observers.

## ISSUES TO BE ADDRESSED

9. The Committee may wish to consider that Recommendations are only required for the three types of health claims, listed in Guidelines on the Use of Nutrition Claims adopted by Codex (CAC/GL 23-1997 Rev. 2001, 2004). Whether a health claim should be granted pre-market approval or how responsibilities are shared between competent authorities and industry in the provision and updating of scientific evidence are beyond the scope of this paper. Generally, the procedural or organisational issues should be left for national competent authorities to decide upon.

10. The Committee may wish to confirm that the scope of the document should not be expanded beyond what already adopted Codex Guidelines require and to request the Electronic Working Group to concentrate on the elaboration of a concise set of principles.

11. All Members, having commented in writing, recognise, although some Observers do not, that the Scope of the Recommendations should cover both scientific of health claim and additional safety concerns, raised by the use of such claims on food.

12. The Committee may wish to confirm its agreement on this approach.

13. Some Members have suggested a basic scheme as broadly applicable; it is made up of three steps: (1) define a physiological or behavioural endpoint (biomarker); (2) define an enhanced component of the diet and (3) monitor the relation between the two.

14. The Committee may wish to consider whether this approach is used as the main basis of the Recommendations.

15. All Members and Observers, having submitted written comments, agree about "grades of [scientific] evidence" and that nature of scientific evidence vary with different types of claims. All Members require "significant scientific consensus" (SSA); however some Observers point out the usefulness to acknowledge "emerging science". All Members stress that health claims should be substantiated using studies on humans (preferably, clinical studies); other types of evidence may be only used in support of the evidence provided by studies on humans.

16. The Committee may wish to consider whether the approach followed on the use of scientific evidence and the emphasis on human studies are appropriate for all types of health claims.

17. The comments point out that health claim may be used in a broad range of cases: Diet/food group/food/food component/substance added to the food. They note that the different substantiation standards may apply to different cases: basically, health claims applied to whole diet and/or food group are set apart from those about food and food components. On the other hand, comments by Members show a definite trend toward recommending more stringent standards of scientific evidence. Moreover, they point out that the terminology, used in the current draft, is not entirely consistent; some Members and Observers have provided suggestions for improvement in this regard. It appears that if the maximum breath of coverage were maintained, the complexity of the paper would be greatly increased.

18. Noting that this issue is closely related to the approach has agreed on for two former items, the Committee may wish to request the electronic working group (1) to restrict the scope of the Recommendations to health claims applied to food/food component/substance added to a food and (2) to assess the adequacy of the various terms, suggested in some written comments, in this context, in order to ensure overall consistency during the next revision of the draft.

19. All Members, having commented in writing, recognise the need to re-evaluate health claims. There is some disagreement on how such a requirement be framed to be practicable (reassessment at regular intervals is not supported) and not too onerous (as every new studies published may not add significant new findings).

20. The Committee may wish to request the Electronic Working Group to consider this issue in more detail.

21. Member Governments and interested International Organisations are invited to comment on the issues above and should do so in writing to the addresses indicated above **not later than 31 March 2006.**